

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/13551

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A01N 45/00(2006.01);A61K 31/56(2006.01)

USPC: 514/171

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/171

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,776,923 A (LABRIE) 07 July 1998 (07.07.1998), abstract, columns 27-28.	1-20
Y	US 2003/0022877 A1 (DUDLEY) 30 January 2003 (30.01.2003), abstract, page 5, paragraphs 0 [0039]-[0043].	1-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 July 2006 (22.07.2006)

Date of mailing of the international search report

07 AUG 2006

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 06045965 A		Date of mailing (day/month/year) 07 AUG 2006 FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US06/13551	International filing date (day/month/year) 11 April 2006 (11.04.2006)	Priority date (day/month/year) 12 April 2005 (12.04.2005)	
International Patent Classification (IPC) or both national classification and IPC IPC: A01N 45/00(2006.01);A61K 31/56(2006.01) USPC: 514/171			
Applicant UNIMED PHARMACEUTICALS, INC.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 22 July 2006 (22.07.2006)	Authorized officer Leonard M. Williams Telephone No. (571) 272-1600
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Form PCT ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US06/13551

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US06/13551

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-20</u>	NO
Industrial applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Labrie (US Patent No. 5776923). Labrie teaches, in the abstract, steroid precursors for use in the treatment and/or prevention of vaginal atrophy, hypogonadism, diminished libido, osteoporosis, urinary incontinence, ovarian cancer, uterine cancer, skin atrophy, for conception, and in combination with an estrogen or progestin for the treatment of menopause. The compositions are to be formulated into gels, solutions, creams, ointments and transdermal patches for percutaneous and transdermal administration. Pharmaceutical compositions and kits are contemplated. In column 27 line 55-column 28 line 45, examples are topical compositions are taught including example 15 wherein a gel contains 10% DHEA, 5% propylene glycol, 0.2% Carbomer 940, 40% water, 0.2% triethanolamine, 2% PPG-12-Butyl-16, 1% hydroxypropyl and 41.6 % ethanol.

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Dudley (US 2003/0022877). Dudley teaches, in the abstract, methods, kits, combinations, and compositions for treating, preventing or reducing the risk of developing a testosterone deficient disorder via administration of a steroid in the testosterone synthetic pathway. In paragraphs 0039-0043, Dudley teaches topical applications of testosterone compositions to females for treatment of testosterone deficiency. The testosterone can be formulated as an hydroalcoholic gel and can include penetration enhancers, stabilizers, fragrances, etc....

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.